

**2376**

**REVIEW OF AND RESPONSE TO U.S. EPA AND  
OEPA COMMENTS ON PROPOSED CHANGES TO  
THE RI/FS QAPJP**

**08/16/91**

**ASI/DOE-FO  
19  
MEMORANDUM**

## MEMORANDUM

2376

To: Oba Vincent  
From: Larry A. Sexton  
Date: August 16, 1991  
Subject: Review of and Response to U.S. EPA and OEPA Comments on Proposed Changes to the RI/FS QAPjP

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The following responses have been prepared after receipt of open comments from U.S. EPA and OEPA for proposed changes to the RI/FS QAPjP.

DCR #8      Revision of rinsate collection frequency for surface water, groundwater, sediments and subsurface soils

U.S. EPA      A new DCR will be issued to provide the requested change for surface water, groundwater and sediment sampling only. The subsurface soil samples will be reviewed to determine the frequency and analysis of past rinsate events. The review will be used to see if any cross contamination was evidenced. The results of this review should be available by September 30, 1991. The RI/FS QAPP will be corrected to the original rinsate sampling requirement for subsurface soil sampling.

OEPA          Direction will be requested from DOE and U.S. EPA to increase sampling frequency from 20 to 10 events. Current compliance is to U.S. EPA SW-846 minimum and is the RI/FS approved frequency requirement.

DCR #11      Requested addition of laboratories to perform analysis of RI/FS sampling

U.S. EPA      The RI/FS project is currently scheduling review of procedures and audits of the listed laboratories for compliance to requirements of the RI/FS QAPP. The audit and procedure review will be for technical and quality control requirements. Requests will be prepared for the U.S. EPA audit of these laboratories.

DCR #12      Revision of field collection form

U.S. EPA      Was approved by U.S. EPA. As noted, the need to provide groundwater temperature measurements on the field records is done by the project.

DCR #20      Revision of RI/FS QAPP Section 15.0 to allow use of ASI audit procedure instead of the IT procedure.

U.S. EPA      Copies of the DCR, changed pages and copies of the ASI audit procedures are attached for U.S. EPA and OEPA review and comment.

DCR #28      Revision to Section 15.0 Document Control

OEPA            Currently the form identified in Figure 15-2, page 9 of 14 requires U.S. DOE to identify when U.S. EPA is to be notified of changes to the RI/FS Work Plan.

DCR #64      Data Validation Plan Addendum

U.S. EPA        A review of past and current U.S. EPA and OEPA comments is being performed for  
OEPA            incorporation or comment by September 15, 1991.

LAS6938DM7

pc:     D. Carr            Project File  
         J. Wood

# RI/FS DOCUMENT CHANGE REQUEST

This form is used to initiate and update  
RI/FS plans and procedures, only.

SAFETY	
YES <input type="checkbox"/>	NO <input checked="" type="checkbox"/>
INVOLVED	

REQUEST NO: <u>20</u>
Completed by: _____
Revision/ Issue Date: _____
DO NOT WRITE IN THIS BLOCK

2376

REQUESTOR John Savage PHONE NO.: (615) 483-1274 DATE Nov. 7, 1988  
DOCUMENT TITLE QAPP; Revision 3 DOCUMENT NUMBER Volume V  
SECTION/PARAGRAPH/PAGE NO.: Section 12.0/3rd paragraph/pg. 1 of 4  
ISSUE DATE January 1987 LATEST REVISION DATE March 1988

JUSTIFICATION Assignment of ASI-QA Officer requires auditing to be performed in accordance with the responsible organization's requirements.

CONTENT OF CHANGE Change 3rd paragraph to read as follows:

"Audits for this project will, as appropriate, cover laboratory activities, field operations and documentation, and final reports. Auditing will be performed in accordance with the applicable section(s) of the Advanced Sciences, Inc. (ASI) Quality Assurance Manual. Internal laboratory audits are also discussed in Laboratory-Specific Attachments."

## CANCELLATION INSTRUCTIONS

CANCEL DOCUMENT NO.: N/A  
Reason for cancellation: \_\_\_\_\_

## REQUIRED APPROVALS

R. T. Wilde 12-2-88  
ASI PROJECT DIRECTOR/DATE  
Robert M. McDaniel 12/5/88  
ASI QA OFFICER/DATE  
N/A 10/1/88  
IT PROJECT DIR./DATE  
IT QA OFFICER/DATE

N/A 1/11/89  
WMCO PROJECT MGR./DATE  
N/A 1/11/89  
WMCO IMPACT ASSESS. MGR./DATE  
A. E. Richardson 1/11/89  
WMCO QA OFFICER/DATE  
Mary E. Stone 3/15/89  
DOE CONTR/DATE

## 12.0 QUALITY ASSURANCE AUDITS

To verify compliance with QAPP requirements, the QA officer and other technically qualified personnel (if required) will perform planned and documented audits of project activities. These audits will consist, as appropriate, of an evaluation of QA procedures and the effectiveness of their implementation, an evaluation of work areas and activities, and a review of project documentation. Audits will be performed in accordance with written checklists and, as appropriate, technical specialists. Audit results will be formally documented and sent to project director and supramanagement.

Audits may include, but not be limited to, the following areas:

- o Field operation work procedures and records;
- o Laboratory testing and records;
- o Equipment calibration and records;
- o Identification and control of samples;
- o Numerical analyses;
- o Computer program documentation and verification;
- o Transmittal of information; and
- o Record control and retention.

"Audits for this project will, as appropriate, cover laboratory activities, field operations and documentation, and final reports. Auditing will be performed in accordance with the applicable section(s) of the Advanced Sciences, Inc. (ASI) Quality Assurance Manual. Internal laboratory audits are also discussed in Laboratory-Specific Attachments."

An individual audit plan shall be developed to provide a basis for each audit. This plan shall identify the audit scope, activities to be audited, audit personnel, any applicable documents, and the schedule. The plan shall be consistent with the project scope of work schedule, and requirements.

Advanced Sciences, Inc. Corporate Quality Assurance Staff Procedures	ASI	Procedure <u>QASP 18.1</u> Rev. <u>0</u> Date _____ 2376 Page <u>1</u> of <u>5</u> Approved _____ Corporate QA Officer
Title: AUDITS		

## 1.0 PURPOSE

This procedure establishes the responsibility and methods for scheduling, planning, conducting, reporting and follow-up/closure of audits performed by Advanced Sciences, Inc. (ASI).

## 2.0 SCOPE

This procedure applies to audits of ASI divisions, offices, programs, and projects for which the Corporate Quality Assurance Officer (CQAO), or designee, has been assigned audit responsibility.

All sections of this procedure apply to the Fernald Project except in those cases where sections are noted by "FP." These sections are supplemented with Fernald Project-Specific Audit Requirements located in Appendix 1.

## 3.0 DEFINITIONS

Audit - A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. Audits should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.

## 4.0 PROCEDURE

### 4.1 Schedule and Frequency

- 4.1.1 The CQAO/designee shall schedule audits as early in the life of a project/program as practical to provide coverage and coordination with on-going quality and program activities.
- 4.1.2 Schedules shall be developed annually. They shall be reviewed quarterly and revised/updated as necessary to ensure adequate audit coverage. The CQAO approves audit schedules for issue.
- 4.1.3 The schedule format is shown in Attachment A.
- 4.1.4 An audit frequency shall be established to ensure evaluation of all program elements within the desired time frame.

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4.1.5 Audit schedule and frequency shall be developed by considering the following items, as appropriate:

- Project schedule, associated work breakdown structure activities, and assignments
- Status and importance of the activity or item
- Previous audit results and corrective actions
- Changes in organizational structure
- State and federal regulatory changes
- Any substantial change in the QA program
- Suspicion that performance, quality, or reliability is in jeopardy.

4.1.6 Scheduled audits may be supplemented by unscheduled audits as deemed necessary.

4.1.7 Schedules and their revisions shall be distributed to organizations and personnel as identified by the CQAO or his/her designee.

#### 4.2 Team Selection

4.2.1 The CQAO selects audit team members based upon their expertise in the areas to be audited.

4.2.2 Every team shall have a certified lead auditor designated as the Audit Team Leader (ATL).

4.2.3 Audit team members shall have had no direct responsibility for performing the activities being audited.

#### 4.3 Planning

4.3.1 The ATL, or designated team member, shall prepare an audit plan (see Attachment B).

4.3.2 The ATL shall coordinate audit planning with the audit team prior to conduct of the audit.

4.3.3 The ATL shall provide written notification of scheduled audits to the management of the audited organization. Notification shall be given two weeks prior to the audit date and include as a minimum:

- Audit date(s)
- Audit subject and scope
- Team members
- Personnel to be contacted by name and/or title
- Required work space
- Time and place of pre-audit meeting
- Documents and/or items requested to expedite the conduct of audit

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4.3.4 The ATL and/or designee(s) prepares an audit checklist (see Attachment C). Each checklist item (or group of items) shall reference the governing document requirement:

- Preparation of checklists is based upon review of existing procedures, previous audit/surveillance results and applicable requirements
- Checklist items shall be of sufficient detail to permit evaluation of objective evidence for compliance

4.3.5 The ATL assigns a five alpha-numeric identifier in accordance with the following:

X X X X X

Sequential audit number, 01 being the first audit of the calendar year.

Last two digits of the calendar year, (i.e., 91 for 1991)

Alpha indicator to distinguish between corporate and project audit (i.e., "C" for corporate audit; "F" for Fernald Project audit, etc.). The CQAO designates other project indicators as required.

#### 4.4 Audit Performance

4.4.1 Audit meetings shall be conducted by the ATL.

- The pre-audit meeting provides for review of the plan, scope and purpose of the audit; personnel introductions; the establishment of personnel contacts; identification of actions required to expedite audit execution; and tentative scheduling of post-audit meeting.
- The post-audit meeting provides for a brief presentation of audit results; discussion of identified findings/observations; and arrangements for timely corrective action.
- Pre- and post-audit meeting attendance shall be documented. Documentation includes audit number; meeting type, date and time; and attendee's name (printed and signed), organization, and title.

4.4.2 Audits are performed in accordance with prepared checklists.

4.4.3 Audit results, including observations and findings identified, shall be documented on the audit checklist.

4.4.4 Conditions requiring immediate corrective action shall be promptly reported to the management of the audited organization.

4.4.5 During the audit and upon its completion, the auditors will discuss the findings and observations with the individuals audited.

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#### 4.5 Reporting

- 4.5.1 The ATL is responsible for the development and issuance of the audit report in accordance with Attachment F and accomplishing the actions described below. The ATL may delegate responsibility for actions except as noted.
- FP 4.5.2 Audit findings and observations shall be identified on forms as shown, respectively, in Attachments D and E. Findings and observations shall be sequentially identified by adding numerical and alpha suffixes, respectively, to the audit number (i.e., C9101-1, C9101-2, and C9101-A, C9101-B, etc.).
- 4.5.3 The audit report shall explain any differences (e.g., expansions and/or reductions) between the planned and performed audit scopes. This is to be noted in both sections 5 and 6 of the report.
- 4.5.4 Audit reports shall be signed and dated by the audit team members and approved by the ATL.
- 4.5.5 Audit reports shall be distributed to the audited organization management within thirty (30) calendar days from the date of the exit meeting.
- 4.5.6 Distribution shall be by cover letter, in accordance with Attachment G. The ATL signs cover letters except for corporate audits which are signed by the CQAO.

#### 4.6 Follow-up and Closure

- FP 4.6.1 The ATL performs follow-up actions to verify that corrective action is accomplished.
- FP 4.6.2 Upon completion of acceptable corrective action, closure of the finding and/or observation shall be documented on the respective forms by the ATL.
- 4.6.3 The ATL notifies, in writing, the audited organization management and the person tracking Corrective Action status of all findings/observation closures.

#### 4.7 Audit Action Logging

- 4.7.1 Each auditing organization shall designate a person to track audit and Corrective Action status.
- 4.7.2 The ATL provides finding/NCR/observation status and audit closure status to the person tracking action status.
- 4.7.3 Corrective Action status shall be maintained on the Corrective Action Tracking Log, Attachment H.

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## 5.0 RECORDS

5.1 Audit records shall be maintained in the location(s) designated by the CQAO.

5.2 Audit records to be maintained are:

- Audit schedules
- Audit plans
- Audit notification memoranda
- Audit reports with cover letter
- Completed checklists
- Written replies (e.g. closed findings/observations)

## 6.0 ATTACHMENTS

- A - Audit Schedule Form
- B - Audit Plan Form
- C - Audit Checklist Form
- D - Audit Finding Sheet
- E - Audit Observation Sheet
- F - Audit Report Format
- G - Audit Report Cover Letter Format
- H - Corrective Action Tracking Log

## 7.0 APPENDICES

- 1 - Fernald Project-Specific Audit Requirements

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## ATTACHMENT A

## Audit Schedule Form

PROJECT - Fernald FMPC	FY 1991												FY 1992		
	AUDIT SCHEDULE														
PROGRAM ELEMENT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
Organization & QA Program															
Field Procedures															
Sample Collection															
Chain-of-Custody															
Equip. Calib. & Maintenance															
Lab Analytical Procedures															
Data Reduction, Validation, & Reporting															
QC Checks & Frequency															
Surveillances															
Preventive Maintenance															
Assessment of Data Precision, Accuracy & Compliance															
Document Control															
Nonconformances/Corrective Action/Variances															
Reports to Management															
Records Administration															
Data Base Management															
F = Field      L = Lab															
Audit Identification _____															
Prepared By: _____ Date: _____	Comments: _____	Approved By: _____ Date: _____ Revision: _____	Legend: S = Scheduled      P = Performed R = Report Written      C = Findings Closed ( ) = Follow up to Corrective Action												

## Audit Plan Form

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Prepared By \_\_\_\_\_ Date \_\_\_\_\_

Approved By \_\_\_\_\_ Date \_\_\_\_\_

## Audit Checklist Form

### QUALITY ASSURANCE CHECKLIST

Organization Audited: _____			DATE OF AUDIT: _____	
Audit Area: _____			AUDIT NO. _____	
Applicable Documents: _____ _____				
AUDIT ITEM	REFERENCE DOCUMENT	ACC	REJ	AUDITOR COMMENTS

**Auditor** \_\_\_\_\_

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## ATTACHMENT D

## Audit Finding Sheet

QUALITY ASSURANCE PROGRAM AUDIT FINDINGS		AUDIT NO.: _____ FINDING NO.: _____ AUDIT DATE: _____ PAGE ____ OF ____	
AUDIT LOCATION:		FINDING SUBJECT:	
PERSON(S) CONTACTED:		AUDITOR:	
CONTROLLING DOCUMENT:	SECTION:	PARAGRAPH:	REV. NO.: DATE:
DESCRIPTION OF THE REQUIREMENTS:			
DESCRIPTION OF THE FINDINGS:			
AUDITEE PROPOSED CORRECTIVE ACTION:			
SCHEDULED COMPLETION DATE: _____			
CORRECTIVE ACTION TAKEN:			
DATE COMPLETED:		PROJECT MANAGER:	
PROPOSED CORRECTIVE ACTION: SAT _____ UNSAT _____		AUDITOR: _____ DATE: _____	
COMPLETION VERIFICATION: SAT _____ UNSAT _____		METHOD OF VERIFICATION:	
AUDITOR: _____		DATE: _____	

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## ATTACHMENT E

## Audit Observation Sheet

QUALITY ASSURANCE PROGRAM AUDIT OBSERVATION	AUDIT NO.: _____ OBSERVATION NO.: _____ AUDIT DATE: _____ PAGE ____ OF ____
AUDIT LOCATION:	OBSERVATION SUBJECT:
PERSON(S) CONTACTED:	AUDITOR:
DESCRIPTION OF THE OBSERVATION:	
AUDITEE PROPOSED CORRECTIVE ACTION:	
SCHEDULED COMPLETION DATE: _____	
CORRECTIVE ACTION TAKEN:	
DATE COMPLETED:	PROJECT MANAGER:
PROPOSED CORRECTIVE ACTION: SAT _____ UNSAT _____	AUDITOR: _____ DATE: _____
COMPLETION VERIFICATION: SAT _____ UNSAT _____	METHOD OF VERIFICATION:
AUDITOR: _____	DATE: _____

## AUDIT REPORT

- Audit Team Member \_\_\_\_\_  
Signature Date

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## ATTACHMENT G

## Audit Report Cover Letter Format

(Use ASI Letterhead)

TO: Division/Program/Project Manager

FROM: CQAO for Corporate Audits/ ATL for Project Audits

DATE: Audit Report Issue Date

SUBJECT: Name of division/program/project facility audited, name of audited organization, audit number and dates

The results of a [corporate or project] quality assurance audit conducted [audit dates] at the [facility name] are documented in the attached audit report. Please respond to the audit finding(s) by [establish a date 30 days from the expected receipt of the report]. Your response should address: 1) actions taken to correct the specific problem(s) identified; 2) identification of root cause of the problem(s); 3) a check for similar problem(s) in similar areas; and, 4) measures taken to prevent recurrence of the problem(s). The responses should be for each individual problem and include an anticipated completion date for the proposed corrective action. Please type your response directly on the applicable audit finding/observation form and return the original(s) to me for evaluation and follow-up.

If you have any questions or comments concerning the audit, please direct them to [CQAO or ATL].

cc: Audited Organization Immediate Management  
 Audited Organization Division Management  
 CQAO  
 Audit Team Members  
 Others  
 Appropriate File

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## ATTACHMENT H

## Corrective Action Tracking Log

CORRECTIVE ACTION TRACKING LOG								
Document Number	Originator	Date Originated	Date Rem. Action Due	Date ATPR Due	Responsible Manager Approved	C/A Verified Date	Item Closed By	Key Word
1.	2.	3.	4.	5.	6.	7.	8.	9.

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## ATTACHMENT H

## Instructions for Corrective Action Tracking Log

Item No.

- 1 Enter the identification number of the originating document (i.e., the document that requires corrective action(s) being taken, such as Nonconformance Reports, Audit findings and observations, Surveillance findings and observations).
- 2 Enter initiator's name.
- 3 Enter date initiated.
- 4 Enter date for completing remedial action(s)
- 5 Enter date for completing action(s) to prevent recurrence (ATPR).
- 6 Enter date that responsible manager approved the corrective action(s).
- 7 Enter the date the corrective action(s) were verified/completed.
- 8 Enter item closure date.
- 9 Enter key words to describe corrective action(s) to be taken.

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## APPENDIX 1

## Fernald Project-Specific Audit Requirements

Requirements of this procedure apply to audits of Fernald Project activities with the exceptions as described below. These define Fernald Project-Specific Audit Requirements. The paragraph identification follows the format of the procedure.

- 4.5.2 Audit findings shall be documented on Project Nonconformance Reports (NCRs). The audit report shall identify findings by subject and with reference to the associated NCR number. Audit observations shall be identified on the form as shown in Attachment E. Observations shall be identified sequentially by alpha suffix to the audit number (i.e., C9101-A, C9101-B, etc.).
- 4.6.1 The PQAO performs initial follow-up of audit finding NCRs to verify that corrective action has been completed and notifies the ATL of the follow-up results.
- 4.6.2 The ATL may, if desired, process the closure of the finding based upon the PQAO's transmittal of a copy of the closed NCR.